K012640

Medical Instruments Technology Inc.

FEB 2 8 2002

Quality Reprocessing and Surgical Cost Containment Systems

Section 12: 510k Summary

Name of Submitter

Medical Instruments Technology, Inc.
385 North 3050 East
Saint George, UT 84790
Tel: (435) 674-4010
Fax: (435) 674-9819

Contact persons

Tom Haueter, RA/QA Manager
Crystal Batcabe, Assistant RA/QA Manager

Summary Prepared August 10, 2001

Device Name and Classification

Common Name: Electrosurgical Cutting and Coagulation Accessories, Electrosurgical Wands
Classification: Class II per 21 CFR 878.4400

Predicate Device

MIT's reprocessed electrosurgical cutting and coagulation accessories are substantially equivalent to: Mitek (K974022) or Arthrocare Wands (K962321)

Description of Device

The cutting and coagulation system consists of a system controller that is connected to a power source. Two cables extend from the system controller, one to a foot-pedal to allow the operator to control the device; the other cable leads to the wand portion, which functions in the surgical site. The wand is the accessory for which MIT has developed the reprocessing technology.

Intended Use

The intended use of the cutting and coagulation accessory is to ablate tissue and/or cauterize. The devices are indicated for use in joints such as, ankles, knees, hips, wrist, elbow, and shoulders. They are supplied sterile.

Technological Characteristics

MIT's reprocessed electrosurgical devices have the same technological characteristics as the predicate devices. MIT does not change any of the design characteristics or materials during reprocessing. The only material change, that MIT does make, it that of the sheathing. The sheathing is replaced, because the original sheathing would be damaged in the reprocessing procedures. The replacement sheathing is substantially equivalent to the original sheathing, and actually acts as a better electrical insulator as shown in the dielectric test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Mr. John P. Batcabe
Development Manager
Medical Instruments Technology, Inc.
385 North 3050 East
Saint George, Utah 84790

Re: K012640
Trade/Device Name: Reprocessed Electrosurgical Wand
Regulation Number: 888.1100, 878.4400
Regulation Name: Arthroscope
Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: HRX, GEI
Dated: December 4, 2001
Received: December 11, 2001

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012640

Medical Instruments Technology, Inc's.
Reprocessed Electrosurgical Wand Premarket Notification

Section 3: Indications for Use

Intended Use:
MIT 's unique reprocessing of the wands does not change their intended use. The intended use of the cutting and coagulation accessory is to ablate tissue and/or cauterize. The devices are indicated for use in joints such as, ankles, knees, hips, wrist, elbow, and shoulders.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012640